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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,425	06/06/2007	Todd C. Zankel	30610/39385A	5100

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Marshall, Gerstein & Borun LLP (Biomarin)
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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1657

NOTIFICATION DATE	DELIVERY MODE
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06/24/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/588,425	Applicant(s) ZANKEL ET AL.	
	Examiner Kailash C. Srivastava	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-35 is/are pending in the application.
- 4a) Of the above claim(s) 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/26&05/14/2007 and 10/03/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Response and remarks filed 27 April 2010 to Office Action with Election/Restriction requirement mailed 30 March 2010 is acknowledged and entered.

Claims Status

2. According to the Preliminary Amendment filed on 15 June 2009, the Claims status is as follows:

⌚ Claims 1-30 have been cancelled;

⌚ Claims 31-35 have been added;

Election/Restriction

3. Applicants' election without traverse of Group I invention encompassing Claims 31-34 is acknowledged and entered. Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, Claim 35 is withdrawn from further consideration as being directed to a non-elected invention. See 37 C.F.R. §1.142(b) and M.P.E.P. § 821.03.

Priority

4. Applicants' claim for domestic priority under 35 U.S.C. § 119(e) to Provisional U.S. Application Serial Numbers 60/542,586, filed 06 February 2004 is acknowledged.
5. Applicants' claim for domestic priority under 35 U.S.C. §371 to PCT/US05/04345 filed 07 February 2005 is acknowledged.

Information Disclosure Statement

6. Information Disclosure Statements filed respectively on 26 March and 14 May 2007 and on 03 October 2008 are acknowledged, have been made of record, have been considered and duly initialed PTO FORMS 1449 or equivalent are enclosed with the instant Office Action.

Specification Objected

7. The specification is objected to because on the first page of specification, in its present

form the recitation for the Cross-Referenced Related Applications does not list all the applications to which the Priority Claim has been claimed. Appropriate correction to perfect the claim for priority is required.

Double Patenting

8. The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

9. Claims 31-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-2 of co-pending U.S. Patent Application Number 12/182,818. Although, conflicting claims are not identical, they are not patentably distinct from each other because claims 1-2 of referenced U.S. Patent Application are drawn to a composition comprising rhGAA variants of 90-95% sequence identity, and thus the same ingredients as claimed in the recited claims of instant application. It would have been obvious to one of ordinary skill in the art to replace the components disclosed in the above-cited co-pending U.S. Patent Applications with the recombinant enzyme claimed in the instant application. Thus, the instant claims are obvious variants of the claims presented in the co-pending U.S. Patent Applications recited *supra*.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections – 35 U.S.C. § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 31-34 are rejected under 35 U.S.C. §102(b) as anticipated by Amalfitano et al (2001. Recombinant human acid α - glucosidase enzyme therapy for infantile glycogen storage disease type II: Results of a phase VII clinical trial. Genetics in Medicine, Volume 3, Number 2, Pages 132-138 Applicants' IDS filed 10/03/2008).

Claims 31-34 recite a composition comprising a human recombinant acid α - glucosidase enzyme (i.e., rhGAA), wherein:

- ▲ at least 70% of said rhGAA binds to the cation-independent mannose-6-phosphate receptor through phosphorylated oligosaccharides;
- ▲ rhGAA has a minimum quantity of bis- phosphorylated oligomannose;
- ▲ at least one molecule of complex oligosaccharide from among galactose, acetylglucosamine, sialic acid and other sugars in place of high mannose oligosaccharide;
- ▲ has half maximal concentration of ≤ 10 nM upon being taken up into a fibroblast cell; and
- ▲ comprises a pharmaceutically acceptable carrier, diluent or excipient.

Regarding Claims 31-34, Amalfitano et al., teach a composition comprising rhGAA purified from rhGAA secreting Chinese hamster ovary (i.e., CHO) cells. Said rhGAA was administered to the patients suffering from a lysosomal disease. Thus, said composition comprised a pharmaceutically acceptable carrier, diluent or excipient. Even though Amalfitano et al., are silent regarding said rhGAA's specific properties listed *supra* and Claimed in Claims 31-33; Amalfitano et al., anticipate said subject matter and said features described in Claims 31-33 because the rhGAA that Amalfitano et al. administer to said patients is the same component as is instantly claimed and would therefore inherently have the properties that are in instantly claimed Claims 31-33 (See e.g., *In re Best*, 195 USPQ 430, 433-CCPA 1977).

Therefore, the reference is deemed to anticipate the cited claims 31-34.

Conclusion

12. For the aforementioned reasons, no claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Kailash C Srivastava/
Examiner, Art Unit 1657

Kailash C. Srivastava
Patent Examiner
Art Unit 1657
(571) 272-0923

18 June 2010

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657